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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/785,230	02/25/2004	Tadamitsu Kishimoto	046124-5042-01	1453
9629	7590	05/18/2006	EXAMINER	
MORGAN LEWIS & BOCKIUS LLP 1111 PENNSYLVANIA AVENUE NW WASHINGTON, DC 20004			GODDARD, LAURA B	
			ART UNIT	PAPER NUMBER

1642

DATE MAILED: 05/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/785,230

Applicant(s)

KISHIMOTO ET AL.

Examiner

Laura B. Goddard, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS; WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 1-24, 27, 29 and 30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25, 26 and 28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 09/646,785.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 6/16/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. The Election filed February 28, 2006 in response to the Office Action of August 30, 2006 is acknowledged. Applicant elected with traverse Group XVII (claims 25, 26, and 28) drawn to a method for treating a solid tumor or suppressing neovascularization comprising administering a substance that inhibits binding between the ligand SDF-1 and the receptor CXCR4.

Applicants argue that the invention of Group XVIII is performed with the therapeutic agents of claims 1-23, and that Group XVIII and claims 1-23 are related inventions and a search of the claims of Group XVIII would reveal the relevant art for claims 1-23, thus it would not be a burden to search and examine claims 1-23 with the claims of Group XVIII (see Remarks, p. 2).

The argument has been considered and is not found to be persuasive because the products of claims 1-23 include therapeutic agents with different structures and different functions such as inhibiting signaling from CXCR4 to nuclei, inhibiting expression of CXCR4, and inhibiting expression of SDF-1 that would not be used in the specific method of inhibiting binding between the ligand SDF-1 and receptor CXCR4. The product used in the method of Group XVIII is distinct from the process of using the product because the product can be used in materially different processes as stated in the Office Action of August 30, 2006, p. 8 to 9. A search for one group is not required for another group, and the Groups encompassing claims 1-23 and Group XVIII have different classifications, hence a search of the Groups encompassing claims 1-23 and

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Group XVIII would invoke a high burden of search. For these reasons, the restriction requirement is deemed to be proper and is therefore made FINAL.

Claims 1-30 are pending. Claims 1-24, 27, 29, and 30 are withdrawn from further consideration by the examiner under 35 CFR 1.142(b) as being drawn to non-elected inventions. Claims 25, 26, and 28 are currently under prosecution.

Priority

2. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 09/646,785, filed on 2/16/2001.

Specification

3. The specification is objected to for the following reason: The specification on page 1 should be amended to reflect the most current priority status of the present application, including proper reference to applications that have been issued or abandoned. For example, US Application No. 09/646,785 filed 2/16/2001, is now abandoned.

Claim Objections

4. Claim 25, 26, and 28 are objected to because of the following informalities: Claims 25 and 26 recite "a substance that inhibits the action due to CXCR4" and it is grammatically unclear what the "action due to CXCR4" is. Claim 28 recites "a substance

that inhibits the action of CXCR4" and it is unclear what the "action of CXCR4" is.

Amendment of claims 25, 26, and 28, for example, to recite "a substance that inhibits CXCR4" may obviate the objection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 25, 26, and 28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. THIS IS A WRITTEN DESCRIPTION REJECTION.

The claims are drawn to a method of treating a solid cancer or a method for treating disease pathologically caused by neovascularization comprising administering a **substance** that inhibits the action due to CXCR4 to a mammal in need thereof (claims 25 and 26), and a method for suppressing vascularization comprising administering a **substance** that inhibits the action of CXCR4 in a mammal in need thereof, wherein the **substance** inhibits the binding between the ligand SDF-1 and the receptor CXCR4 (claim 28).

The specification discloses that there are no particular limitations to substances that inhibit the action due to CXCR4 (p. 16, lines 11-15). The specification discloses that for a substance that inhibits the binding itself between SDF-1 and CXCR4, there are a substance that inhibits SDF-1 and a substance that inhibits CXCR4 (p. 16, lines 23-26). The specification discloses substances that inhibit SDF-1 from binding to CXCR4 by binding to SDF-1 such as an anti-SDF-1 antibody, fragment thereof possessing binding activity, a fused protein possessing binding activity to SDF-1, a substances that induces structural change in SDF-1, a low-molecular weight compound that binds to the CXCR4-binding site of SDF-1, and the like (p. 17, lines 13-20). The specification discloses substances that inhibit CXCR4 such as soluble CXCR4 that antagonizes CXCR4 in inhibition, a protein having a CXCR4-like structure, a low molecular weight compound having a structure similar to a partial peptide of CXCR4 or a binding site of CXCR4, and the like (p. 17, lines 21-26 to p. 18, lines 1-8). Examples of substances that inhibit the binding itself between CXCR4 and SDF-1 include T22, ALX40-4C, AMD3100, and the like (p. 18, lines 17-22). The specification does not disclose any other **substances** that inhibit the action due to CXCR4 or inhibit the binding between the ligand SDF-1 and the receptor CXCR4 as broadly encompassed in the claims.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any

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structure/function correlation, methods of making the claimed product, or any combination thereof. There is no identification of any particular portion of the structure that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Drawn to DNA arts, the findings in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) and Enzo Biochem, Inc. V. Gen-Probe Inc. are relevant to the instant claims. The Federal Circuit addressed the application of the written description requirement to DNA-related inventions in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). The court stated that "[a] written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name', of the claimed subject matter sufficient to distinguish it from other materials." Id. At 1567, 43 USPQ2d at 1405. The court also stated that:

a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA" without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is.

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Id. At 1568, 43 USPQ2d at 1406. The court concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id.

Finally, the court addressed the manner by which a genus of cDNAs might be described. "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." Id.

The Federal Circuit has recently clarified that a DNA molecule can be adequately described without disclosing its complete structure. See Enzo Biochem, Inc. V. Gen-Probe Inc., 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002). The Enzo court adopted the standard that "the written description requirement can be met by show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristicsi.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." Id. At 1324, 63 USPQ2d at 1613 (emphasis omitted, bracketed material in original).

Thus, the inventions at issue in Lilly and Enzo were DNA constructs per se, the holdings of those cases are also applicable to claims such as those at issue here. A disclosure that does not adequately describe a product itself logically cannot adequately describe a method of using that product.

Thus, the instant specification may provide an adequate written description of substances, per Lilly by structurally describing representative substances or by describing "structural features common to the members of the genus, which features constitute a substantial portion of the genus." Alternatively, per Enzo, the specification can show that the claimed invention is complete "by disclosure of sufficiently detailed, relevant identifying characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics."

In this case, the specification does not directly describe substances in a manner that satisfies either the Lilly or Enzo standards. Although the specification discloses examples of substances such as T22, ALX40-4C, AMD3100, this does not provide a description of the broadly claimed substances that would satisfy the standard set out in Enzo because the specification provides no functional characteristics coupled to structural features.

Further, the specification also fails to describe substances by the test set out in Lilly because the specification describes only examples of substances such as T22, ALX40-4C, AMD3100. Therefore it necessarily fails to describe a representative number of such species.

Thus, the specification does not provide an adequate written description of substances that is required to practice the claimed invention. Since the specification fails to adequately describe substances, it also fails to adequately describe the method.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 25, 26, and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,563,048 (Honjo et al, issued 10/8/1996, filed 10/14/1994, IDS) (see sequence search result #1, issued patent database).

The claims are drawn to a method of treating a solid cancer or a method for treating disease pathologically caused by neovascularization comprising administering a substance that inhibits the action due to CXCR4 to a mammal in need thereof (claims 25 and 26), and a method for suppressing vascularization comprising administering a substance that inhibits the action of CXCR4 in a mammal in need thereof, wherein the substance inhibits the binding between the ligand SDF-1 and the receptor CXCR4 (claim 28).

For the purposes of interpreting the claims, the specification teaches (page 16, lines 11-15) that there are no limitations to substances that inhibit the action due to CXCR4. This includes (page 17, line 14+) substances that inhibit SDF-1 from binding to CXCR4 such as anti-SDF-1 antibodies or modified SDF-1 proteins, i.e. SDF-1 structure-resembling proteins" (specification, page 33, line 10+). As for a "mammal in need thereof", the specification contemplates (page 38, lines 19+) the administration of the

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substance to several distinct populations including those having solid tumors, chronic articular rheumatism, psoriasis, and diabetic retinopathy.

Honjo et al. broadly teach SDF-1 polypeptides (abstract, and column 1; and see sequence search result #1, issued patent database wherein SEQ ID NO:1 has 100% homology the SDF-1 SEQ ID NO:5 of the instant application) and the use of such polypeptides as pharmaceutical compositions comprising anti-SDF-1 antibodies or polypeptides of the invention (column 2, lines 64+). Polypeptides of the invention, as defined by Honjo et al., include SDF-1 "structure-resembling" polypeptides (column 3, lines 1+). Honjo et al. further teach the use of said polypeptides for disease relating to abnormal proliferation of hematopoietic cells (which reads on the abnormal formation of blood cells such as neovascularization) including use of the polypeptides to a mammal in need thereof wherein said mammals may include members of a populations that have cancer or inflammatory diseases such as rheumatoid arthritis (column 5, line 28 to column 6, line 1). Although the prior art does not specifically teach that the use of said substances "suppress vascularization", "treat a disease caused by neovascularization", or "inhibit the action due to CXCR4", Honjo et al. teach the use of such substances to administer to a mammal in need thereof including those populations having cancer or inflammatory conditions such as rheumatoid arthritis. Therefore, such administration of the pharmaceutical compositions comprising anti-SDF-1 antibodies or SDF-1 "structure-resembling" polypeptides would inherently suppress vascularization, treat a disease caused by neovascularization, and inhibit the action due to CXCR4 in a mammal in need thereof. The office does not have the facilities and resources to provide the factual

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evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed substances).

In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed substance is different from those taught by the prior art and to establish patentable differences. See *In re Best* 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

7. **Conclusion:** No claims are allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura B. Goddard, Ph.D. whose telephone number is (571) 272-8788. The examiner can normally be reached on 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


JEFFREY SIEW
SUPERVISORY PATENT EXAMINER

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Laura B Goddard, Ph.D.
Examiner
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